



Government of **Western Australia**
Department of **Health**

Department of Health Human Research Ethics Committee

Annual Report 2019

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1. Background

The Department of Health Human Research Ethics Committee (DOH HREC) was established in April 2008 to oversee the use and disclosure of personal health information held in the Department of Health's (Department) data collections.

The objectives of the DOH HREC are to:

- promote the ethical use of health information
- promote ethical and scientific standards of human research
- protect the welfare, rights and dignity of individuals, as well as the privacy and confidentiality of their personal health information (including health information) and
- facilitate ethical research through efficient and effective review processes.

The DOH HREC is registered with the National Health and Medical Research Council (NHMRC) and is constituted in accordance with the National Statement on Ethical Conduct in Human Research 2007 (National Statement). The NHMRC collates information about HRECs and monitors their compliance with the National Statement and with sections s95 and s95A of the *Privacy Act 1988*.

This report is presented in accordance with the reporting obligations in the DOH HREC Terms of Reference and provides a summary of the DOH HREC activities from 1 January 2019 to 31 December 2019. It includes information on its members and their expertise, the number of applications submitted to the DOH HREC and their status, the number of complaints received and the predominant users of the data collections.

In 2017, a centralised IT system (called the Research Governance Service, RGS) was adopted by WA Health. The purpose of the RGS is to enable the completion, submission, administration, tracking and reporting of research projects through their life cycle including ethics approval, site authorisation, monitoring and publications. It is mandatory for all researchers, project members, site administrators, Human Research Ethics Committees and Research Governance Offices to use this system to manage applications for ethics and governance approval that involve WA public health organisations.

2. Membership

Members are appointed to fulfill specific roles as per the National Statement and the Terms of Reference. As a minimum, HRECs in Australia comprise of:

- a Chairperson with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement
- at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work
- at least one person with knowledge of, and current experience in, the professional care, counselling and treatment of people
- at least one member who performs a pastoral care role in the community, for example a minister of religion or an Aboriginal elder
- at least one lawyer who is not engaged to advise the institution
- at least two people with current research experience that relates to research proposals to be considered at the meetings they attend.

The DOH HREC is a specialist committee that oversees the use of personal health information held by the Department. To ensure it has the expertise to perform this function the Terms of Reference require that the Committee also include:

- at least one person with knowledge of and current experience in information security, and
- at least one person with knowledge of and current experience in the management and uses of large health data collections who is employed by the WA health system.

At the conclusion of 2019 one member's term expired. Seventeen members had terms renewed and one new member was recruited for 2020. In previous years, members were renewed for a one year term only due to the State Government's review of Boards and Committees. The DOH HREC provided information for this review and in particular noted the gender representation within the committee. For 2019 there were:

- Sitting members (10 members) 4 males and 6 females
- Deputy members (9 members) 5 males and 3 females.

The staggered approach to appointing members to fixed term positions has previously ensured the continuity of experience and knowledge within the DOH HREC. Sitting members may serve one term and deputy members may serve two consecutive terms. Deputy members with comparable expertise and experience are appointed to the DOH HREC as proxies when sitting members are unable to attend meetings.

Table 1 shows the DOH HREC Sitting Members with Deputy Members in Table 2 for 2019.

Table 1: Sitting members serving on the DOH HREC in 2019

Position	<i>Incumbent</i>
Chairperson	Dr Peter Bentley
WA health system representative	Mr Stephen Woods
Information security	Mr Shane Gallagher
Lay person	Ms Kathryn Kirk
Lay person	Mr Phillip Jacobsen
Lawyer	Ms Jennifer Wall (term expired December 2019)
Pastoral care	Prof Colleen Hayward
Professional care	Ms Natalie Fleetwood
Researcher	Dr Alison Reid
Researcher	Dr Angela Ives

Table 2: Deputy members serving on the DOH HREC in 2019

Position	<i>Incumbent</i>
WA health system representative	Mr Richard Gillett
Information security	Mr Bret Watson
Lay person	Ms Sonia McKeiver
Lay person	Mr John McMath
Lawyer	Ms Nadia Saba
Pastoral care	<i>Vacant</i>
Professional care	Clinical Associate Professor Ann McDonald
Researcher	Professor Satvinder Dhaliwal
Researcher	Associate Professor Richard Brightwell

3. Training

Newly appointed sitting and deputy members are provided with an induction that focuses on the: (i) role and scope of the DOH HREC; (ii) National Statement; (iii) information about the DOH data collections and data linkage; and (iv) legal obligations pertaining to health data. New members attend an induction workshop as well as an HREC meeting to observe the meeting processes. All members received training on the RGS and will continue to do so.

4. Meetings and executive support

The DOH HREC meets on the second Wednesday of every month. In 2019, 11 meetings were held.

A quorum for meetings of the DOH HREC exists when at least five members are physically present and include one of each of the following categories:

- chairperson/deputy chairperson
- lay person
- researcher, and
- at least one third of those present being from outside the Department.

A quorum was met for all the meetings in 2019.

An Ethics Executive Officer employed by the Department provided administrative support to the DOH HREC.

5. Review of research projects

The number of new applications considered by the DOH HREC in 2019 and the status of these applications are tabulated in Table 3. The titles of these new applications are shown in Appendix A.

Table 3: Number and status of new applications from 1 January to 31 December 2019

Total applications received in 2019	39
Approved applications	36
Rejected	0
Withdrawn	0
In progress	3

The DOH HREC received 39 new applications during the reporting period. As shown in Table 3, of these applications, 36 were approved in 2019, three were still in progress by 31 December 2019 prior to HREC review.

Table 4 outlines the number of reports, applications and amendment requests received from 2015 – 2019. There was an increase in the number of new applications and the number of annual progress reports. The number of amendment requests decreased. There was a notable decrease in the number of final reports.

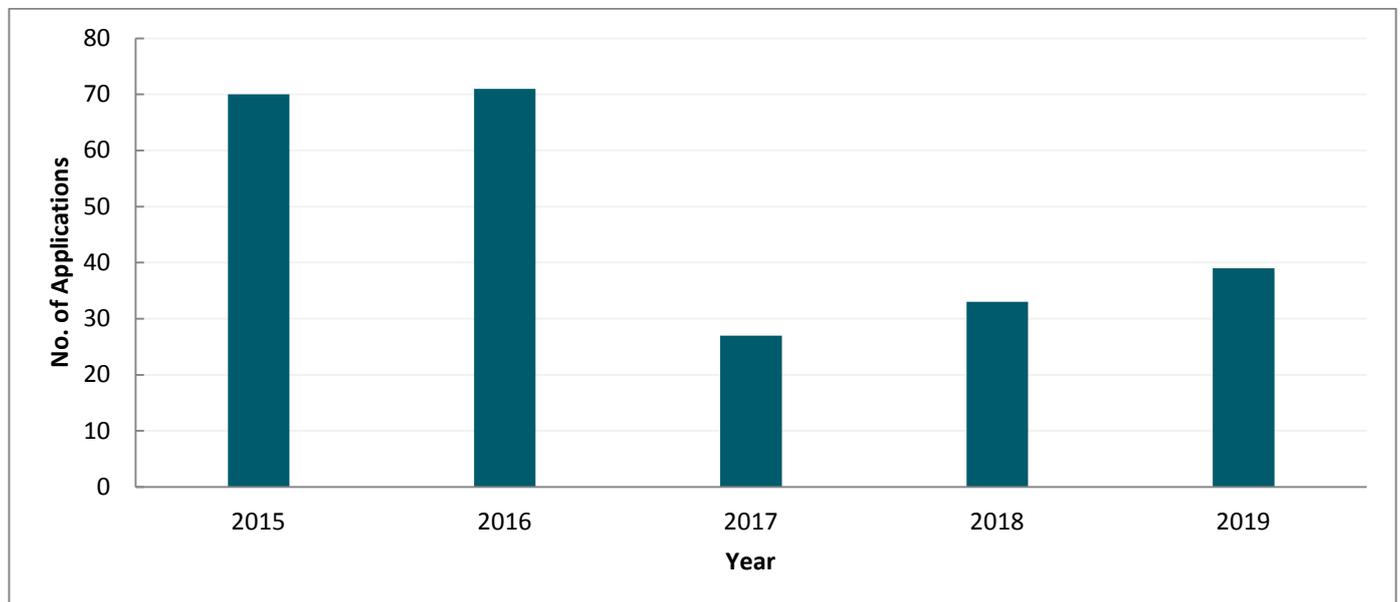
The RGS was implemented in 2017, at that time there was a noticeable decline in the number of ethics submissions. Since then, there has been a gradual increase in the number of submissions.

Table 4: Number of requests received 2015 – 2019

Year	2015	2016	2017	2018	2019
New Applications	70	71	27	33	39
Annual reports	120	83	96	159	163
Amendment Requests	175	148	194	218	204
Final Reports	17	9	22	99	15

Figure 1 shows the number of new applications considered by the DOH HREC by calendar year for the last five years.

Figure 1: Applications reviewed by DOH HREC 2015 – 2019



6. Annual reports, amendments and final reports

The DOH HREC is bound by the NHMRC guidelines to monitor the progress of all approved projects until completion. This is in accordance with chapter 5.5 of the National Statement ensuring that research conducted conforms to the approved ethical standards.

In accordance with chapter 5.5.3 of the National Statement, researchers have a significant responsibility in monitoring their research. Researchers must report any serious unexpected, adverse or unforeseen events that might affect the continued ethical acceptability of the project.

Researchers are responsible for ensuring that an annual report, amendment requests and a final report are submitted to the DOH HREC in a timely manner. The templates for the required reports are accessible in the Research Governance Service.

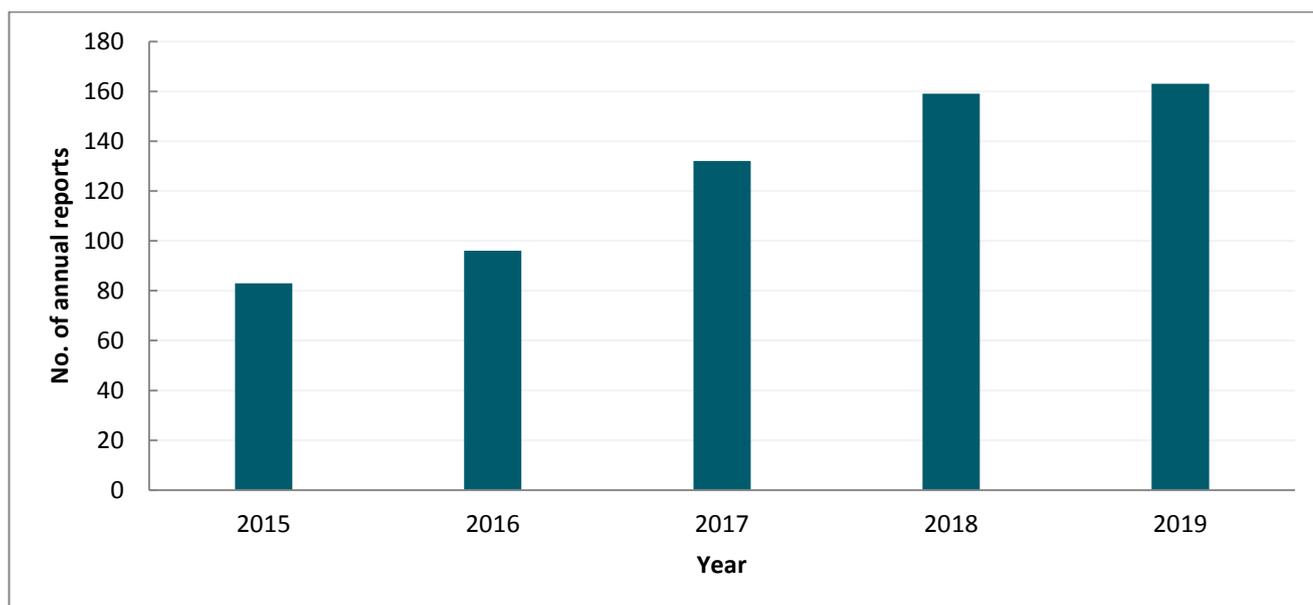
Annual reports

The standardised annual report requires researchers to provide the following information about the approved project:

- progress to date, publication or outcome in the case of completed research
- maintenance and security of records and data
- compliance with the approved protocol
- compliance with the conditions of approval
- changes to the protocol or conduct of the research
- changes to the personnel or contact details of the principal investigator, and
- adverse events or complaints relating to the project.

A total of 163 annual reports were approved by the DOH HREC in 2019. As of December 2019, the RGS has implemented an automated tracking system to contact researchers when they are due to submit a report. Ongoing ethics approval will be dependent on researchers submitting their reports in a timely manner. Figure 2 shows the total number of annual reports approved between 2015 and 2019.

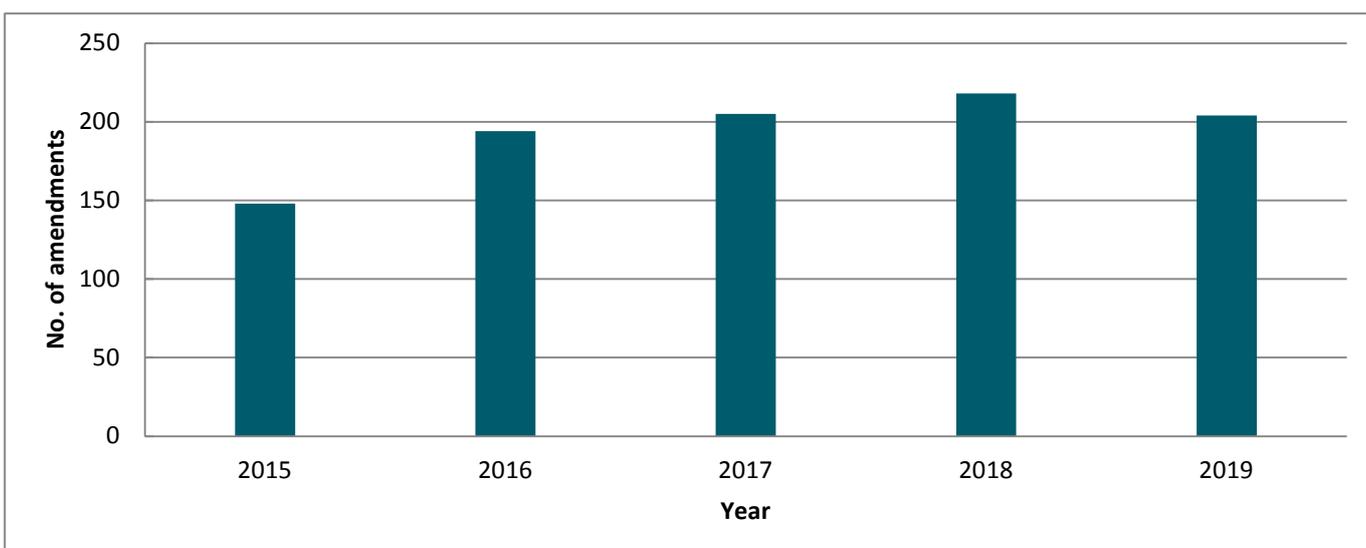
Figure 2: Total number of annual reports approved by DOH HREC 2015 – 2019



Amendments

Researchers are required to complete the standard amendment request form when seeking approval for changes to the research protocol including methodology, data required, duration of the project, changes to personnel in the research team and changes to the approved data storage arrangements. Extensions were often requested to facilitate further research publications or due to delays obtaining data. A total of 204 amendment requests were approved by the DOH HREC in 2019, which is on par with amendments approved in 2018 (with 218 approved amendment requests). Figure 3 shows the total number of amendment requests approved between 2015 and 2019.

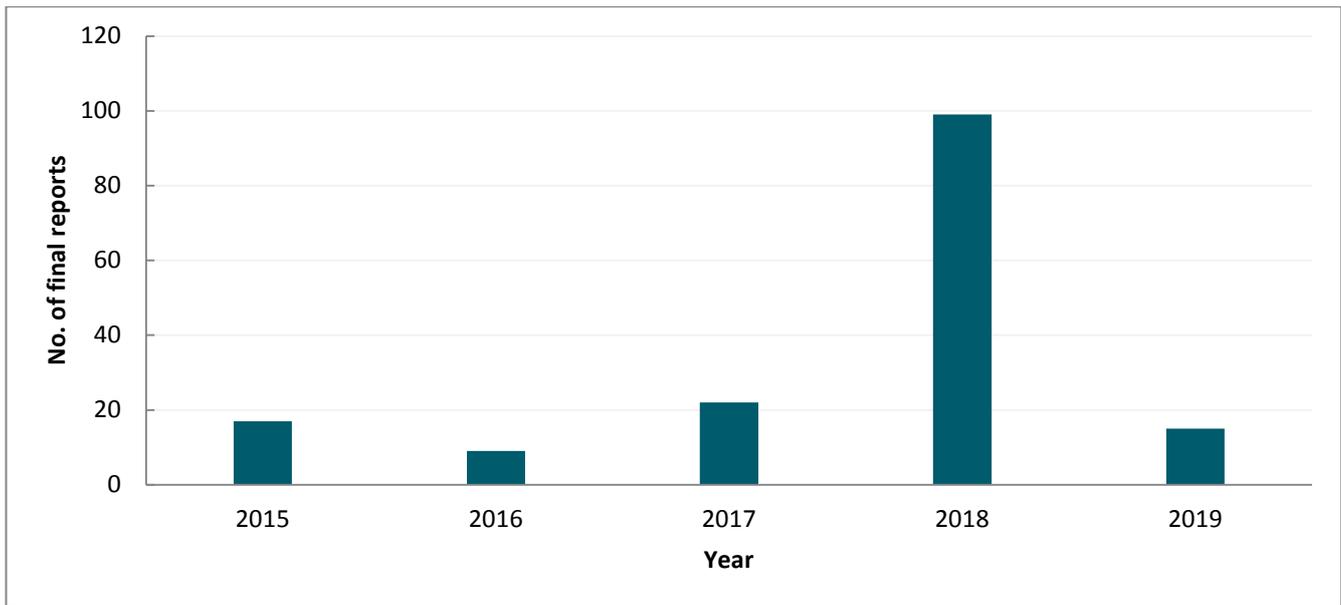
Figure 3: Total number of amendment requests approved by DOH HREC 2015 – 2019



Final reports

A final report is required to be submitted at the completion of the research project. The report includes the outcomes of the research, a copy of the results and any publications. A total of 15 final reports were submitted and approved in 2019. The average number of final reports submitted and approved over the last five years is 32. Figure 4 shows the total number of final reports approved between 2015 and 2019. The high number shown in 2018 was a result of actively pursuing researchers to submit their final reports after an audit had been carried out, which showed that many researchers had not fulfilled their reporting requirements.

Figure 4: Total number of final reports approved by DOH HREC from 2015 – 2019



7. Administrative procedures

The Ethics Executive Officer provides administrative support for the operation of the DOH HREC and is responsible for ensuring that applications are received and processed in accordance with the Standard Operating Procedures (SOP).

The Ethics Executive Officer is also responsible for ensuring that all applications and other documentation such as agendas, minutes and correspondence are maintained in accordance with the *State Records Act 2000*.

Throughout 2019 the DOH HREC Office undertook an audit of all research projects whose ethical approval was requiring closure. Researchers had a two-step process to submit a final report or request an extension of ethical approval. Researchers who failed to respond to the DOH HREC Office had their projects terminated. The audit assisted with the migration of current DOH HREC projects to the RGS.

8. Breaches, concerns and complaints

The DOH HREC SOP outlines the process for receiving, handling and responding to complaints concerning:

- concerns and complaints about the conduct of a project approved by the DOH HREC (SOP17), and
- breaches in the conduct of a project approved by the DOH HREC (SOP18)
- reporting and handling of adverse events in clinical trials (SOP19)
- the DOH HREC's review or rejection of an application (SOP26).

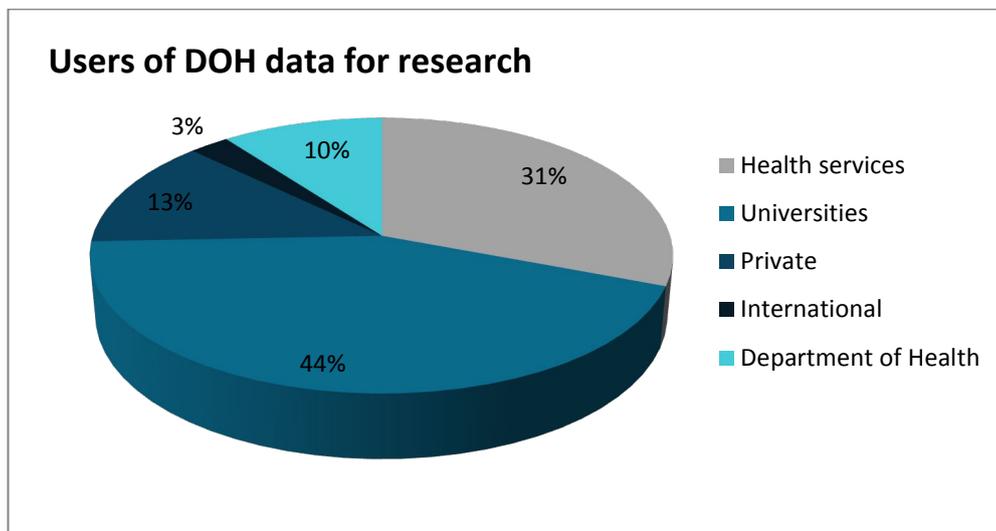
There were five notifications of concern raised with the Committee relating to unauthorised release of data and participant consent. The Chair examined each complaint and was satisfied that no further investigations were required.

9. Users of the Department of Health's data for research

Applications for data for research from the Department's data collections and registers in 2019, came from Universities (44%), Health services (31%), private sector (13%), Department of Health (10%) and overseas (3%).

Figure 5 shows the breakdown by users of the Department's research data for 2019.

Figure 5: Breakdown by users of DOH data for research in 2019



10. Application of Privacy Act 1988 guidelines

There are specific situations where the Guidelines approved under Section 95 of the *Privacy Act 1988* (section 95 guidelines) and the Guidelines approved under Section 95A of the *Privacy Act 1988* (section 95A guidelines) need to be applied to the review of research projects. Specifically, these guidelines apply to disclosure of personal health information from Commonwealth agencies or the private sector.

The Guidelines under Section 95 of the *Privacy Act 1988* apply to medical research which involves the use of personal health information held by a Commonwealth agency without the consent of the individual.

The Guidelines under Section 95A of the *Privacy Act 1988* apply if personal health information is required from an organisation in the private sector without the consent of the individual and any of the following uses applies:

- research relevant to public health or to public safety, and/or
- the compilation or analysis of statistics, and/or
- the conduct of the management, funding or monitoring of a health service.

In considering the guidelines, the DOH HREC must be satisfied that it is necessary for the research to use identified or potentially identifiable data and, that it is impracticable to obtain consent (s95A Guidelines), or that it is reasonable for the research to proceed without the consent of the individuals to whom the information relates (s95 Guidelines).

In reaching a decision, the DOH HREC must also consider whether the public interest in the research and the likely benefits outweigh the public interest in privacy. In 2019, the DOH HREC applied the section 95 guidelines to one application (RGS0000003530). The section 95A guidelines were applied to two applications (RGS0000003187 and RGS0000003511). All three applications were granted ethics approval.

11. Public awareness

The DOH HREC takes the view that it is important that members of the public are aware of the ways in which personal health information, collected by the Department, is used for the public benefit. Accordingly, the DOH HREC has initiated the quarterly publication on the DOH HREC website of brief summaries of all research projects approved by the Committee. Publication of the summaries commenced in 2012 and project summaries for approved proposals are available at http://ww2.health.wa.gov.au/Articles/A_E/Department-of-Health-Human-Research-Ethics-Committee

12. Conclusion

In 2019, the DOH HREC discharged its responsibilities to oversee the use and disclosure of personal health information held in the Department data collections. The combined skills and expertise of the Committee members and deputy members were applied to the ethical review of 39 new projects.

The Committee works closely with data custodians, the Data Services team and the Research Governance Unit to ensure that researchers comply with the National Statement on Ethical Conduct in Human Research. Together they ensure that the welfare, rights and dignity of individuals are taken into consideration and that the privacy and confidentiality of any personal information requested, is protected. It is necessary that all human research projects are well developed, ethical and have scientific merit. The Committee aims to continue being responsive and accessible to researchers.

13. Supporting documents

[Department of Health \(2018\). Department of Health Western Australia Human Research Ethics Committee Terms of Reference. Department of Health, Perth.](#)

[Department of Health \(2018\). Department of Health Western Australia Human Research Ethics Committee Standard Operating Procedures. Department of Health, Perth.](#)

[National Health and Medical Research Council \(2000\). Guidelines approved under Section 95 of the *Privacy Act 1988*. Commonwealth of Australia. Canberra.](#)

[National Health and Medical Research Council \(2001\). Guidelines approved under Section 95A of the *Privacy Act 1988*. Commonwealth of Australia. Canberra.](#)

[National Health and Medical Research Council \(2007\). National Statement on Ethical Conduct in Human Research. Australian Government. Canberra.](#)

Appendix A – New applications reviewed in 2019

#	PRN	Title
1	RGS0000001267	Cardiac specific biomarkers for risk prediction in the general population
2	RGS0000001402	Epidemiology of invasive beta-haemolytic streptococcal disease in Western Australia
3	RGS0000001488	Health and psychological wellbeing in survivors of childhood cancer in Western Australia: a whole population data linkage study
4	RGS0000003088	Impact of consensus guidelines on margins for breast conserving surgery: translation to clinical care in WA
5	RGS0000000395	Cognitive impairment and TDM2
6	RGS0000000838	The mid and long term clinical outcomes in patients treated with Everolimus- Eluting Bioresorbable Vascular Scaffold in tertiary hospitals of Western Australia
7	RGS0000001195	Evaluation of post-operative care following repair of gastroduodenal ulcer perforation, effect on patient outcomes and development of a new protocol
8	RGS0000001386	Economic evaluation of influenza vaccination in WA
9	RGS0000001442	Comparing syntocinon regimen outcomes
10	RGS0000001701	Biomarkers for cardiovascular disease, diabetes and renal outcomes in an Australian population
11	RGS0000003021	How is birth by caesarean section delivery associated with the risk of childhood type 1 diabetes?
12	RGS0000003029	The utilisation and safety of prescription drugs of dependence in pregnancy
13	RGS0000003151	Real world health economic impact of first seizure and newly diagnosed epilepsy
14	RGS0000003188	Development and evaluation of the urban health check
15	RGS0000003198	Impact of comorbidity and time in hospital on time and cost to healing of wounds
16	RGS0000000404	Long-term outcomes after trauma in Western Australia: the determinants of morbidity and mortality after major trauma
17	RGS0000001094	Healthcare costs of heatwaves and benefits of a heat health intervention
18	RGS0000001392	West Australian SMART Application of Blood Culture Initiative (WASABI): Improving the management of patients with serious infection and reducing low value care
19	RGS0000001467	Morbidity outcomes in polycystic ovary syndrome
20	RGS0000003142	Exposure dependent effectiveness of mumps vaccination
21	RGS0000003187	The clinical and economic benefits of early use of clozapine in first episode schizophrenia
22	RGS0000003392	Measles cases that have previously received any measles-containing immunisations: infectivity, clinical characterisation, and reasons for an apparent rise in incidence
23	RGS0000003442	Evaluation of the WA Health 2019 pharmacist influenza vaccination trial
24	RGS0000003511	Visual field impairment and injury: a population-based study
25	RGS0000003530	IBIS-I: A multicentre trial of tamoxifen to prevent breast cancer (long term follow up)
26	n/a	Minimum price on alcohol modelling project
27	n/a	Management of safety concerns regarding textures breast implants

28	RGS0000001263	Sebaceous carcinoma in Western Australia
29	RGS0000001422	Trends in the perinatal diagnosis of congenital heart defects in Western Australia: 2004-2017
30	RGS0000003156	Multicentre randomised controlled trial: caregiver, patient and system outcomes from a program supporting informal caregivers of older people discharged home from hospital
31	RGS0000003249	Describing congenital heart defects in Western Australia: 1980-2016
32	RGS0000003302	Identifying gaps in Hepatitis B screening and management in the Midwest region of Western Australia (WA), and Aboriginal and Vietnamese insights into their understanding of chronic hepatitis B
33	RGS0000003482	Smoke Alert: tracking smoke complaints in the southwest of WA
34	RGS0000003650	Incidence of Ocular Melanoma in Australia: 1982-2015
35	RGS0000003656	Identifying genetic risk factors for cardiovascular disease in extended pedigrees in the Busselton Health Study
36	RGS0000003674	Accuracy and cost-effectiveness of technology-assisted dietary assessment
37	RGS0000003376	Australian hepatitis B and hepatitis C duplicate notifications linkage project
38	RGS0000003462	Using total population data to produce policy-relevant evidence to increase access to services for Aboriginal children with intellectual disability / autism spectrum disorder in Western Australia
39	RGS0000003496	Indigenous child removals Western Australia

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